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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

EPPS, JANET L

ART UNIT	PAPER NUMBER
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1635

DATE MAILED, 01/14/2003

10

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/783,981

Applicant(s)

LECLERCQ ET AL

Examiner

Janet L Epps-Ford, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 31 October 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 23-42 is/are pending in the application.
- 4a) Of the above claim(s) 39-42 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 23-38 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 5. 6) ☐ Other:

DETAILED ACTION***Election/Restrictions***

1. Applicant's election with traverse of Claims 23-38 in Paper No. 9 is acknowledged. The traversal is on the ground(s) that the examiner has not provided any evidence to support a conclusion that the functionalized polyalkyleneamines of Group II can be made by a process materially different from that of Group I. This is not found persuasive because Applicant's specification, page 3, lines 3-8, describe an alternative method for synthesizing a functionalized polyethyleneimine comprising the action of an oligosaccharide with polyethyleneimine in the presence of sodium cyanoborohydride. Therefore, contrary to Applicant's assertions the compositions of claims 39-41 can be obtained using a materially different process than that set forth in claims 23-28. Furthermore, Applicants argue, "there is no teaching or suggestion in WO 97/42285 that a similarly functionalized polyalkyleneimine according to claims 39-41, comprising targeting elements and nucleic acids, can be used as a soil-releasing agent." However, Applicant's arguments do not take the place of evidence that the polyalkyleneimines disclosed in the specification as filed, can not be used for the same purpose as the polyethyleneimines disclosed in WO 97/42285 (see page 15). Although the compositions of claims 39-41 comprise a nucleic acid, there is no evidence that the presence of the nucleic acid molecule somehow changes the inherent properties of the preferred polyethyleneimine (see page 5, line 25, of the specification as filed) used in the compositions of the present invention.

The requirement is still deemed proper and is therefore made FINAL.

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2. Claims 39-42 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 9.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 34-38 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 34, and those claims dependent thereon, recite a functionalized hemiacetyl having the general formula as set forth in claim 34, wherein n is 0 or 1. This formula is vague and indefinite since there is no "n" variable recited in the formula. Claim 34 recites wherein R1, R2, R3, R4 are a group "compatible with the reaction carried out." This phrase is vague and indefinite since it is unclear how one of skill in the art would be able to ascertain the full scope of compounds that are "compatible with the reaction carried out." Additionally, Claim 34 recites wherein R1, R2, R3, R4 are a "targeting element." This phrase is also vague and indefinite since it is unclear what the element, in this context, is intended to target. Finally, there is lack of antecedent basis for the term "hemiacetyl" in claim 23, the correct term intended by Applicants may have been, for example, "hemiacetal."

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Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claims 23-33 rejected under 35 U.S.C. 103(a) as being unpatentable over Zanta et al. in view of Neidgh et al.

Claims 23-33 recite: (23) a process for making functionalized polyalkyleneimines, comprising treating a polyalkyleneimine with a functionalized hemiacetal in the presence of titanium (IV) isopropoxide and sodium borohydride; (24) the process according to claim 23, further comprising an alcoholic solvent, (25) wherein the alcoholic solvent is methanol or ethanol; (26) the process according to claim 23, which is performed at a temperature between about 10°C and about 30°C; (27) the process according to claim 23, wherein between about 25 mol and about 100 mol of titanium (IV) isopropoxide are used per mol of polyalkyleneimine; (28) the process according to claim 23, wherein a molar amount of sodium borohydride is used equal to between 50% and 80% of the molar amount of titanium (IV) isopropoxide; (29) the process of claim 23, wherein between about 6 mol and about 100 mol of functionalized hemiacetal are used per mol of polyalkyleneimine; (30) the process of claim 23, wherein the polyalkyleneimine has the general formula according to formula (I) or (II); (31) The process according to claim 30, wherein the polyalkyleneimine is polyethyleneimine or polypropyleneimine; (32) the process according to claim 31, wherein the polyethyleneimine has an average molecular weight of about 50,000 Da, about 25,000 Da, or about 22,000 Da; (33) the

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process according to claim 31, wherein the polypropyleneimine has an average molecular weight of about 8000,000 Da.

Zanta et al. teach a method for functionalization of polyethyleneimine. This method comprised the glycosylation of polyethylenimine (PEI, Mw of 43 Da) with the disaccharides lactose or maltose by dissolving the PEI with the disaccharide in sodium borate buffer, addition of sodium cyanoborohydride, incubation at 40°C, cooling and ultrafiltration. (page 840, 1st paragraph).

However, the method of Zanta et al. does not comprise the use of titanium (IV) isopropoxide, and sodium borohydride in an alcoholic solvent. Additionally, Zanta et al. does not specifically teach the following limitations: (27) the process according to claim 23, wherein between about 25 mol and about 100 mol of titanium (IV) isopropoxide are used per mol of polyalkyleneimine; (28) the process according to claim 23, wherein a molar amount of sodium borohydride is used equal to between 50% and 80% of the molar amount of titanium (IV) isopropoxide; (29) the process of claim 23, wherein between about 6 mol and about 100 mol of functionalized hemiacetal are used per mol of polyalkyleneimine;

Neidigh et al. teach the preparation of N-methyl secondary amines by reductive amination of aldehydes (wherein R is H of Scheme 1, hemiacetal) or ketones (where R is alkyl of Scheme 1), comprising the treatment of carbonyl compounds with methylamine hydrochloride, triethylamine, and titanium(IV) isopropoxide in absolute ethanol with sodium borohydride as the reducing agent (page 2527, paragraph 4). This reaction occurs at 25°C, see Scheme I, page 2527.

It would have been obvious to one of ordinary skill in the art at the time of filing to modify the method for functionalization of polyethyleneimine taught by Zanta et al. with the

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conditions for reductive amination taught by Neidigh et al. comprising the use of titanium (IV) isopropoxide in absolute ethanol with sodium borohydride as the reducing agent. One of ordinary skill in the art at the time of filing would have been motivated to make this modification since the use of the sodium cyanoborohydride reagent in the method of Zanta et al. is compromised by its cost and toxicity, specifically the risk of residual cyanide in the product (see Neidigh et al. page 2527, paragraph 2). The use of the titanium(IV) isopropoxide/ sodium borohydride system for the functionalization of polyethyleneimine presents several advantages over the use of sodium cyanoborohydride, since these reagents are relatively safe, inexpensive, and require no special handling techniques (page 2528, paragraph 3).

Moreover, neither Zanta et al. or Neidigh et al. specifically teach all of the specific concentrations and percentages of the molar amounts of titanium(IV) isopropoxide, or functionalized hemiacetal used in the above described methods for functionalizing polyethylenimine. However, absent evidence to the contrary, it would have been obvious to one of ordinary skill in the art to alter the conditions of a given reaction in order to optimize the results of the reaction. As per MPEP § 2144.05, "[G]enerally, differences in concentration or temperature will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration or temperature is critical. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955).

Therefore, the invention as a whole is *prima facie* obvious over Zanta et al. in view of Neidigh et al.

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Information Disclosure Statement

7. Foreign Patent documents DE 19726186 A, and EP0905254 A2, have not been considered since there was no English translation provided by Applicants.

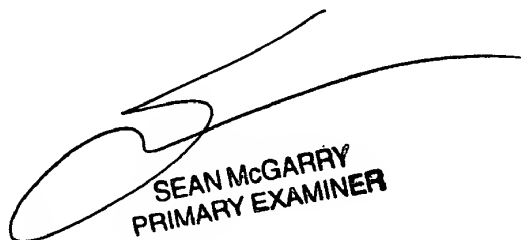
8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Janet L Epps-Ford, Ph.D. whose telephone number is 703-308-8883. The examiner can normally be reached on M-T, Thurs-Friday 9:00AM to 7:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John LeGuyader can be reached on (703)-308-0447. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 for regular communications and 703-746-5143 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Janet L Epps-Ford, Ph.D.
Examiner
Art Unit 1635

JLE
January 9, 2003


SEAN MCGARRY
PRIMARY EXAMINER